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Applicant(s):

Jong Kil et al.

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For:

SYSTEM AND METHOD FOR EMULATING A SURFACE EKG

USING INTERNAL CARDIAC SIGNALS SENSED

BY AN IMPLANTABLE MEDICAL DEVICE

AMENDMENT AND REQUEST FOR RECONSIDERATION

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22213-1450 I hereby certify that this correspondence is being filed electronically on

July 26,2006

Estella Pineiro

Dear Sir:

In response to the Office Action dated May 4, 2006, please amend the above identified application as follows.

In the Claims:

1. (Original) A method for emulating a surface electrocardiogram (EKG) of a patient in which an implantable cardiac stimulation device is implanted, the method comprising:

sensing separate cardiac signals using electrodes implanted within the patient; and

selectively concatenating portions of the separate cardiac signals to yield an emulated surface EKG.

2. (Original) The method of claim 1 wherein sensing cardiac signals comprises:

sensing atrial signals using at least one atrial electrode; and sensing ventricular signals using at least one ventricular electrode.

3. (Currently Amended) A method for emulating a surface electrocardiogram (EKG) of a patient in which an implantable cardiac stimulation device is implanted, the method comprising The method of claim 2 wherein selectively concatenating portions of the cardiac signals comprises:

sensing atrial signals using at least one atrial electrode;
sensing ventricular signals using at least one ventricular electrode;
identifying far-field ventricular signals within the atrial channel signals;
identifying far-field atrial signals within the ventricular channel signals; and
concatenating the far-field atrial signals and the far-field ventricular signals to
yield the emulated surface EKG.

4. (Withdrawn) The method of claim 2 wherein selectively concatenating portions of the cardiac signals further comprises:

determining a value representative of the peak magnitude of the far-field atrial signals;

determining a value representative of the peak magnitude of the far-field ventricular signals; and

adjusting the relative magnitudes of the far-field atrial signals and the far-field ventricular signals so as to achieve a predetermined ratio of peak atrial to peak ventricular magnitudes.

- 5. (Withdrawn) The method of claim 4 wherein the predetermined ratio of peak atrial to peak ventricular magnitude is in the range of 1:4 to 1:10.
- 6. (Withdrawn) The method of claim 2 wherein selectively concatenating portions of the cardiac signals comprises:

identifying near-field atrial signals within the atrial channel signals;

identifying near-field ventricular signals within the ventricular channel signals; and

concatenating the near-field atrial signals and the near-field ventricular signals to yield the emulated surface EKG.

7. (Withdrawn) The method of claim 2 wherein selectively concatenating portions of the cardiac signals further comprises:

determining a value representative of the peak magnitude of the near-field atrial signals;

determining a value representative of the peak magnitude of the near-field ventricular signals; and

adjusting the relative magnitudes of the near-field atrial signals and the near-field ventricular signals so as to achieve a predetermined ratio of peak atrial to peak ventricular magnitude.

- 8. (Withdrawn) The method of claim 7 wherein the predetermined ratio of peak atrial to peak ventricular magnitude is in the range of 1:4 to 1:10.
- 9. (Original) The method of claim 1 wherein sensing cardiac signals using electrodes implanted within the patient comprises:

sensing atrial signals using unipolar sensing by employing an atrial electrode in combination with a housing of the device; and

sensing ventricular signals using unipolar sensing by employing a ventricular electrode in combination with a housing of the device.

- 10. (Original) The method of claim 9 wherein the atrial electrode is a right atrial tip electrode, a right atrial ring electrode, an SVC coil electrode, a left atrial ring electrode, a left atrial coil electrode or a transseptal atrial electrode and wherein the ventricular electrode is a right ventricular tip electrode, a right ventricular ring electrode or a right ventricular coil electrode, a left ventricular tip electrode, a left ventricular ring or a ventricular epicardial electrode.
- 11. (Original) The method of claim 1 wherein selectively concatenating portions of the cardiac signals further comprises:

smoothing the emulated surface EKG at concatenation points.

12. (Original) The method of claim 1 wherein selectively concatenating portions of the cardiac signals further comprises:

aligning signal polarities of the concatenated portions.

- 13. (Original) The method of claim 1 further comprising controlling device functions based, in part, on the emulated surface EKG.
- 14. (Original) The method of claim 1 performed entirely by the implantable medical device.
- 15. (Original) The method of claim 1 performed by the implantable medical device in combination with a device external to the patient, and further comprising transmitting the separate cardiac signals to the external device and wherein selectively concatenating portions of the cardiac signals to yield an emulated surface EKG is performed by the external device.

16. (Currently Amended) A system for emulating a surface electrocardiogram (EKG) of a patient, the system comprising:

one or more electrodes implanted within the patient;

sensing circuitry operative to sense separate cardiac signals using <u>the one or more electrodes [[implanted within the patient]];</u> and

an EKG emulation unit operative to selectively concatenate portions of the separate cardiac signals sensed to yield an emulated surface EKG.

17. (Withdrawn) A method for emulating a surface electrocardiogram (EKG) of a patient in which an implantable cardiac stimulation device is implanted, the method comprising:

sensing far-field atrial cardiac signals using a ventricular electrode;
sensing far-field ventricular cardiac signals using an atrial electrode; and
combining the far-field atrial signals and the far-field ventricular signals to yield
an emulated surface EKG.

18. (Withdrawn) The method of claim 17

wherein sensing far-field atrial cardiac signals using a ventricular electrode is performed by sensing both near-field ventricular signals and far-field atrial signals and then extracting only the far-field atrial signals; and

wherein sensing far-field ventricular cardiac signals using an atrial electrode is performed by sensing both near-field atrial signals and far-field ventricular signals extracting only the far-field ventricular signals.

19. (Withdrawn) The method of claim 17 wherein combining the far-field atrial signals and the far-field ventricular signals to yield an emulated surface EKG comprises:

concatenating the far-field ventricular signals sensed in the atria with the far-field atrial signals sensed in the ventricles.

- 20. (Withdrawn) The method of claim 17 wherein the signals sensed in the ventricles and the signals sensed in the atria are initially high pass filtered and further comprising applying an equalizer to the signals having a transfer function that is substantially the reciprocal of the high pass filter so as to restore low frequency components removed by the filter.
 - 21. (Withdrawn) The method of claim 17 and further comprising: smoothing the combined signals.
- 22. (Withdrawn) A system for emulating a surface electrocardiogram (EKG) of a patient, the system comprising:

first sensing circuitry operative to sense far-field atrial cardiac signals using a ventricular electrode;

second sensing circuitry operative to sense far-field ventricular cardiac signals using an atrial electrode; and

an EKG emulation unit operative to combine the far-field atrial signals and the far-field ventricular signals to yield an emulated surface EKG.

23. (Withdrawn) A system for emulating a surface electrocardiogram (EKG) of a patient, the system comprising:

means for sensing far-field atrial cardiac signals;

means for sensing far-field ventricular cardiac signals; and

means for combining the far-field atrial signals and the far-field ventricular signals to yield a combined signal.

24. (Withdrawn) A method for emulating a surface electrocardiogram (EKG) of a patient in which an implantable cardiac stimulation device is implanted, the method comprising:

sensing near-field atrial cardiac signals using an atrial electrode;

sensing near-field ventricular cardiac signals using a ventricular electrode;

concatenating the near-field ventricular signals with the near-field atrial signals to yield a concatenated signal.

25. (Withdrawn) The method of claim 24 and further comprising: smoothing the concatenated signal at the concatenation points.

REMARKS

Claims 1-3 and 9-16 are currently pending in this application. Applicants have withdrawn claims 4-8 and 17-25 from consideration without prejudice in response to a restriction requirement. Reconsideration is respectfully requested in light of the above amendments and the following remarks.

The Examiner rejected claim 16 under 35 U.S.C. §112, second paragraph as being indefinite. Applicants have amended claim 16 in accordance with the Examiner's suggestions and therefore respectfully request that this rejection be withdrawn.

The Examiner rejected claims 1-2 and 9-16 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,740,811 to Hedberg et al. Applicants respectfully traverse this rejection.

Applicants' claimed invention as recited in claims 1 and 16 is directed to a method and corresponding system for emulating a surface electrocardiogram (EKG) of a patient. For example independent claim 1 recites a method comprised in party by sensing separate cardiac signals ... and selectively concatenating portions of the separate cardiac signals to yield an emulated surface EKG. (Underlining added for emphasis only). Applicants respectfully submit that Hedberg et al. do not disclose or suggest the recited claim elements.

Rather, Hedberg et al. discloses a device and method for generating a synthesized ECG wherein measured <u>signals</u> from <u>two or more</u> intracardiac and/or extracardiac electrodes are <u>combined</u> and a synthesized surface ECG is obtained by subjecting the measured signals to signal processing. The term "<u>synthesized ECG</u>" as used by Hedberg et al. is explicitly defined to mean "a <u>signal generated</u> from <u>at least two</u> in vivo <u>signals</u>, such as at least two IEGMs, which provides the same information as a standard surface ECG." (Hedberg et al., col. 2, lines 57-64).

However, Hedberg et al. process the in vivo signals and then <u>add</u> them together (in their <u>entirety</u>) to form the synthesized signal. Hedberg et al. disclose that the reason for adding the signals from the electrodes is that they will simulate a signal obtained from a bigger electrode. (Hedberg et al. col. 6, lines 63-65). For example, in FIG. 13

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transforming units, which process each of the electrode outputs, are coupled to a combining unit by multipliers which individually weigh each signal under the control of a microprocessor. The <u>combining unit</u> includes a <u>summation stage</u> which <u>sums</u> the outputs of the multipliers (in their entirety) to form the synthesized surface ECG. (Hedberg et al. col. 8, lines 15-50).

Thus, Hedberg et al. process individual signals from separate electrodes and sum them together in their entirety to form an emulated surface ECG. Hedberg et al. do not however, disclose or suggest concatenating (i.e. linking or joining together) portions of the separate cardiac signals to yield an emulated surface EKG as recited in Applicant's claimed invention. Accordingly, Applicants respectfully submit that claims 1, and 16 are novel and non-obvious over Hedberg et al. and are therefore allowable. Applicants further submit that claims 2-3 and 9-15 that depend from claim 1 are allowable as is claim 1 and for additional limitations recited therein.

The Examiner rejected claim 3 under 35 U.S.C. §103(a) as being unpatentable over Hedberg et al. in view of U.S. Patent 5,193,550 to Duffin. Applicants respectfully traverse this rejection.

The Examiner admits that Hedberg et al. do not disclose or suggest sensing far-field atrial and ventricular signals and concatenating portions of these signals to form a synthesized surface ECG as recited in claim 3 of the present application. The Examiner asserts however that Duffin teaches sensing far-field signals to aid in categorizing the source and type of tachyarrhythmias. The Examiner therefore alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method and device for simulating an ECG as taught by Hedberg et al. with the sensing of far field waves taught by Duffin to categorize the source and type of tachyarrhythmia detected.

It is well understood that there must be some suggestion in the references that they be combined to support an obviousness rejection. Merely picking and choosing among various references is not permitted, and doing so amounts to no more than mere hindsight reconstruction. One of ordinary skill in the art must be motivated by the teachings to combine the references, without using applicants' claimed invention as a guide.

The Examiner suggests that the motivation to combine Hedberg et al. and Duffin is allow the system of Hedberg et al. to categorize the source and type of tachyarrhythmias detected. Applicants respectfully disagree. Applicants submit that Hedberg et al. and Duffin are directed at completely different systems. Hedberg et al. like the present invention is directed toward a system for emulating surface ECGs and no where mentions or discloses a system for categorizing detected arrhythmias. Duffin, on the other hand discloses a system and method for discriminating between detected arrhythmias and in no way suggests that these signals can be used to emulate a surface ECG. Therefore, there is no motivation to combine Hedberg et al. with Duffin, since the two references disclose very different systems which are directed to solving very different problems.

Moreover, even if the teachings of Hedberg et al. were combined with those of Duffin one still does not arrive at Applicants' claimed invention because neither Duffin or Hedberg et al. disclose or suggest that far-field signals may be concatenated to form a surface ECG. The mere disclosure by Duffin that far-field signals may be used to discriminate between arrhythmias does not in any way render obvious the use of far-field signals when constructing an emulated surface ECG. Rather, as admitted by the Examiner, the combination of Hedberg et al. and Duffin simply yields a system that is capable of categorizing detecting arrhythmias through the use of far-filed signals, not one that utilizes far-field signals to generate an emulated surface ECG as recited in claim 3. Applicants therefore respectfully submit that claim 3 is novel and non-obvious over Hedberg et al. and Duffin and is therefore allowable.

In light of the above amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

Date

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